PATENT Docket No. 204372000320

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on November 4, 1996

Nancy J. Robins

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Lynn E. Spitler et al.

Serial No.:

08/288,057

Filing Date:

10 August 1994

For:

PROSTATIC CANCER VACCINE

Examiner: P. Gambel

Group Art Unit: 1816

DECLARATION OF MICHAEL MASTRANGELO, MD PURSUANT TO 37 C.F.R § 1.132

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

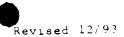
- I, Michael Mastrangelo, MD, declare as follows:
- 1. I am a Professor of Medicine, and Associate Clinical Director of the Jefferson Cancer Center in Philadelphia, Pennsylvania. A copy of my *Curriculum Vitae* is attached hereto as Exhibit A. I am Chairman of the Scientific Advisory Board of Jenner Technologies, the assignee in this application, and a shareholder in the company.
- 2. I have reviewed the Declaration Under 37 C.F.R. 1.132 prepared by Dr. Lynn E. Spitler describing the results of a clinical study directed to the use of prostate specific antigen (PSA) as an active ingredient in an antiprostate cancer vaccine. I am also familiar with the study itself, and with the results that were obtained.

- 3. The purpose of the study was to obtain evidence that the vaccines would raise a sufficient cellular immune response to have a beneficial effect with respect to prostate tumors. Such a result could be shown directly by measuring cytotoxic lymphocyte (CTL) generation, however, I am aware that this was not possible in these studies because the assay was not satisfactory because of the lack of an appropriate target cell for the assay.
- 4. The responses measured are understood in the art to be satisfactory substitutes for measuring CTLs. Thus, the proliferation of lymphocytes from two of the patients in response to contact with PSA or in response to peptides representing putative PSA epitopes is indicative of an appropriate cellular immune response. The ability of PSA or PSA derived peptides to stimulate cytokine production -- i.e., gamma interferon and IL-4 production -- from lymphocytes in these patients also indicates that the cellular response is obtained specifically with respect to PSA. The observation of the development of a positive skin test response to PSA in one patient is also consistent with these observations showing the development of cell-mediated immunity in the patients.
- 5. In my opinion, the results obtained in this clinical study provide evidence that the vaccines are likely to be effective in exerting a beneficial effect on patients with prostate tumors or at risk for prostate tumors.
- 6. The efficacy shown for the vaccine tested in the foregoing clinical studies further provides evidence that analogous vaccines based on host tissue antigen, such as prostate specific membrane antigen (PSMA) and prostate acid phosphatase (PAP) would behave in a similar manner. It is also well known that if the entire antigen is effective as a vaccine, portions of the antigen will be effective as well, especially if manipulated by art-known methods to enhance their immunogenicity, such as by coupling them to carrier.

Thereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

October **10**, 1996

Michael Mastrangelo, MD



CURRICULUM VITAE

NAME: Michael J. Mastrangelo, M	M.D.	SOCIAL	SECURITY N	NO: 210-28-9391
DATE OF BIRTH: October 3, 1938				
MARITAL STATUS: Married 1964 - Children:	Ann Sundav David M. Mark S. Audrey A.	1965 1967 1970		
EDUCATION Villanova University, Villanova B.S. (Biology), Summa Cum The Johns Hopkins University	Laude (1/69	6) Medicine	e, M.D.	1 956- 1960 1 960- 1964
POSTGRADUATE TRAINING Thomas Jefferson University Medical Inter Medical Resid American Canc Oncology Fell Chief Medical Post-doctoral Fellow Laboratory of R. T. Prehn The Institute for Cancer 7701 Burholme Avenue Philadelphia, PA 19111	n ent er Society T ow Resident , M.D.		ohia, PA	1964-1965 1967-1969 1968-1969 1969-1970 1970-1971 1971-1972
MILITARY SERVICE CPT, MC, U.S. Army, Molecula Medical Laboratories, Edg	r Biology Br ewood Arsena	anch, 1, MD		1965-1967
SPECIALTY CERTIFICATION Diplomate of the American Bo Certificate #37358 Diplomate, subspecialty of M Certificate #37358			icine	1972 1973
LICENSURE Maryland - D7736 Pennsylvania - MD 008521-E New Jersey - MA24857				1964 1965 1971
HONORARY SOCIETIES Delta Epsilon Sigma National Collegiate Who's Wh Sigmi Xi	10			1960 1960 1984

Exhibit A

PROFESSIONAL SOCIETIES	1971
College of Physicians of Philadelphia	1972-1986
Philadelphia County Medical Society	1972-1986
Pennsylvania Medical Society	1972-1986
American Medical Association	1972
American Federation for Clinical Research	1973
American Association for the Advancement of Science	1973
American Society of Clinical Oncology	1973
American College of Physicians - Member - Fellow	1975
	1974
American College of Clinical Pharmacology Fellow	1974
American Association for Cancer Research	1979-1980
Program Committee for Immunology - Member - Chairperson	1987-1988
	1984-1985
Membership Committee	1993-1994
Gertrude Elion Award Committee	1981-
Society for Biological Therapy	1988-1991
Board of Directors	1989-1990
Chairman, Program and Publications Committee	1990-1992
President	
PROFESSIONAL ACTIVITIES	1974-
Seminars in Oncology - Associate Editor	1973-1976
Eastern Cooperative Oncology Group - Member	1973-1977
Malignant Melanoma Clinical Cooperative Group - Member	1975-1979
Committee on Tumor Immunotherapy, DCBD, NCI - Member	
American Cancer Society, Philadelphia Division	1975-1977
Member, Professional Education Committee	1978-1979
Member, Board, Northeast Unit	
American Cancer Society, National Office Member, Advisory Committee on Immunology and Immunotherapy	1987-1991
Member, Advisory Committee on Immuno1059	1976-1984
Philadelphia County Medical Society -	1976-1977
Member, Cancer Control Subcommittee	
Experimental Therapeutic Study Section, NIH -	1980-1982
Member	1982-1984
Chairman I + II Cancer Immunology and Immunotherapy - Board of Editors Cancer Immunology and Immunotherapy - Board of the	1981-1993
Cancer Immunology and Immunotherapy Board of the Subcommittee on Biological Response Modifiers of Subcommittee on Biological	1978-1980
Division of Cancer Treatment's Board of Scientific Counsell	ors
Division of Cancer freatment's Board of School	
Biological Response Modifier Program, DCT, NCI -	1980-1982
Operating Committee, Member	1980-1984
Decision Network Committee, Member Journal of Biological Response Modifiers - Editoral Board	1982-1990
Journal of Biological Responde Modaland	1990-
Journal of Immunotherapy - Editorial Board	
n Accordate Editor	1983-1994
Cancer Research - Associate Editor	1987-1992
Hybridoma - Editorial Board	1989-1993
PDQ - Extramural Board PDQ - Extramural Board Convention. Inc.	
The United States Pharmacopeial Convention, Inc. Advisory Panel on Hematologic and Neoplastic Diseases	1990-1995
Vaccine Research - Associate Editor, Tumor Vaccines	1990-
Vaccine Research - Associate Editor, 12-12	

FACULTY AND APPOINTMENTS

Current -	1984-
Professor of Medicine,	1984-1993
Director, Division Medical Oncology	1984-1993
Member, Division Neoplastic Diseases	1993-
Jefferson Medical College	
1025 Walnut Street	
Philadelphia, PA 19107	
Courtesy Staff	1987-
Associate Staff	1984-1987
Associate Physician (Medicine)	1977-1984
Assistant Physician (Medicine)	1972-1976
Director, Pigmented Lesion Clinic	1972-1984
American Oncologic Hospital	
Central and Shelmire Avenues	
Philadelphia, PA	
i miladolphila, i.i.	
Consultant, Oncology	1973-
Department of Medicine	
The Mercer Medical Center	
Trenton, NJ	
	107/
Consultant, Oncology Division	1974-
Retina Service	
Wills Eyes Hospital	
Philadelphia, PA	
Prior	
Instructor (Medicine)	1970-1974
Assistant Physician (Medicine)	1971-1974
Jefferson Medical College and Hospital	
Philadelphia, PA 19107	
	1077 109/
Clinical Associate Professor (Medicine)	1977-1984
Clinical Assistant Professor (Medicine)	1974-1977
School of Medicine	
Temple University Health Science Center	
Philadelphia, PA 19107	
Research Physician	19 72-1980
The Institute for Cancer Research	
Philadelphia, PA	
Intradaphan, In	
Consultant, Medical Oncology	1976-1986
Doylestown Hospital	
Doylestown, PA	
,	
Consultant, Tumor Immunotherapy	1973-1988
Chestnut Hill Hospital	
Philadelphia, PA	

PUBLICATIONS

APERS

- 1. Mastrangelo, M.J., Giordano, W.P. and Johnson, R.P. Surface behavior of individual lipids similar to constituents of pulmonary surfactant. EATR 4087, April 1967.
- 2. Mastrangelo, M.J. and Johnson, R.P. Segmental reversibility and hysteresis of preparations similar to pulmonary surfactant. EATR 4097, May 1967.
- 3. Mastrangelo, M.J., Carwile, H. and Johnson, R.P. Qualitative protein composition of lung surfactant preparations. EATR 4124, August 1967.
- *4. Weiss, A.J. and Mastrangelo, M.J. Phase I study of a combination of azotomycin (NSC-56654) and 5-Fluorouracil (NSC-19893) in malignant disease. Cancer Chemother Rpt. 54:109-112, 1970.
- 5. Mastrangelo, M.J. and Weiss, A.J. The chemotherapy of respiratory tract neoplasms.

 In: Cancer Chemotherapy II, I. Brodsky, S.B. Kahn, J.H. Moyer (Editors), Grune and Stratton, Inc., New York, NY, 1972, pp. 195-208.
- *6. Weiss, A.J., Stambaugh, J.E., Mastrangelo, M.J., Laucius, J.F. and Bellet, R.E. A Phase I study of 5-azacytidine (NSC-102816). Cancer Chemother. Rpt. 56:413-420, 1972.
- 7. Mastrangelo, M.J., Sulit, H.O., Chee, D. and Engstrom, P.F. Cancer Forum: Malignant Melanoma. Penna. Med. 75:43, 1972.
- *8. Mastrangelo, M.J., Grage, T. Bellet, R.E. and Weiss, A.J. A Phase I study of emetine hydrochloride (NSC-33669) in solid tumors. Cancer 31:1170-1175, 1973.
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- *10. Bellet, R.E., Mastrangelo, M.J., Dixon, L.M. and Yarbro, J.W. A Phase I study of ICRF 159 (NSC-129943) in solid tumors. Cancer Chemother. Rpt. 57:185-189, 1973.
 - 11. Mastrangelo, M.J., Creech, R.H. and Engstrom, P.F. Cancer Forum: Early diagnosis holds promise in lung cancer. Penna. Med. 76:64, 1973.
 - 12. Bornstein, R.S., Mastrangelo, M.J., Sulit, H.L., Chee, D.O., Yarbro, J.W., Prehn, L.M. and Prehn, R.T. Immunotherapy of melanoma with intralesional BCG. Natl. Cancer Inst. Monogr. 39:213-220, 1973.
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- *14. Bellet, R.E., Mastrangelo, M.J., Engstrom, P.F., Strawitz, J.G. and Weiss, A.J. Clinical trial with subcutaneously administered 5-Azacytidine (NSC-102816). Cancer Chemother. Rpt. 58:217-222, 1974.

- *16. Bellet, R.E., Mastrangelo, M.J. and Dixon, L.M. Letter to the Editor: ICRF 159. Lancet 1:926, 1974.
- 17. Mastrangelo, M.J., Laucius, J.F. and Outzen, H.C. Fundamental concepts in tumor immunology: A brief review. Semin. Oncol. 1:291-296, 1974.
- *18. Laucius, J.F., Bodurtha, A.J., Mastrangelo, M.J. and Creech, R.H. Bacillus Calmette-Guerin in the treatment of neoplastic disease. J. Reticuloendothel. Soc. 16:347-373, 1974. (Abstracted Year Book of Cancer 1976).
- *19. Bodurtha, A.J., Chee, D.O., Laucius, J.F., Mastrangelo, M.J. and Prehn, R.T. Clinical and immunological significance of human melanoma cytotoxic antibody. Cancer Res. 38:189-193, 1975.
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- *21. Mastrangelo, M.J., Bellet, R.E., Berkelhammer, J. and Clark, W.H., Jr. Regression of pulmonary metastatic disease associated with intralesional BCG therapy of dermal melanoma metastases. Cancer 36:1305-1308, 1975. (Abstracted Year Book of Diagnostic Radiology 1977).
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- *31. Mastrangelo, M.J., Berd, D. and Bellet, R.E. Critical review of previously reported clinical trials of cancer immunotherapy with non-specific immunostimulant. Ann. N.Y. Acad. Sci. 277:94-123, 1976.
- *32. Bellet, R.E., Mastrangelo, M.J., Laucius, J.F. and Bodurtha, A.J. A randomized prospective trial of DTIC (NSC-45388) alone versus BCNU (NSC-409962) plus vincrist (NSC-67574) in the treatment of metastatic malignant melanoma. Cancer Treat. Rpt. 60:595-600, 1976.
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- *34. Bellet, R.E., Catalano, R.B., Danna, V.G., Berkelhammer, J. and Mastrangelo.
 M.J. A study of antitumor (Phase II) and immunosuppressive effects of ICRF-159
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 1976.
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- *39. Bellet, R.E., Vaisman, I., Mastrangelo, M.J. and Lustbader, E. Multiple primary malignancies in patients with cutaneous melanoma. Cancer 40:1974-1981, 1977.

- *40. Laucius, J.F., Bodurtha, A.J., Mastrangelo, M.J. and Bellet, R.E. A Phase
 II study of autologous irradiated tumor cells plus BCG in patients with metastatic malignant melanoma. Cancer 40:2091-2093, 1977.
 - Mastrangelo, M.J., Bellet, R.E., Berd, D., and Lustbader, E. A randomized prospective trial comparing methyl-CCNU + vincristine to methyl-CCNU + vincristine + BCG + allogeneic tumor cells in patients with metastatic malignant melanoma.

 In: Immunotherapy of Cancer: Current Status of Trials in Man, W. Terry and D. Windhorst (Editors), Progress in Cancer Research and Therapy, Vol. 6, Raven Press, New York, NY, 1978, pp. 95-102.
 - Mastrangelo, M.J., Clark, W.H., Jr., Bellet, R.E. and Berd, D. Cutaneous malignant melanoma: Diagnosis prognosis and conventional therapy. <u>In: Immunotherapy of Cancer: Current Status of Trials in Man, W. Terry, D. Windhorst (Editors). Progress in Cancer Research and Therapy, Vol. 6, Raven Press, New York, NY, 1978, pp. 1-17.</u>
 - Engstrom, P.F., Paul, A.R., Catalano, R.B., Mastrangelo, M.J. and Creech, R.H. Fluorouracil versus fluorouracil + BCG in colorectal adenocarcinoma. In: Immunotherapy of Cancer: Current Status of Trials in Man, W. Terry, D. Windhorst (Editors), Progress in Cancer Research and Therapy, Vol. 6, Raven Press, New York, NY, 1978, pp. 587-596.
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 - Berkelhammer, J., Mastrangelo, M.J., Bellet, R.E., Prehn, R.T. and Thibault, L.H. Failure of lymphocyte microcytoxicity to distinguish relapsers from non-relapse in melanoma patients receiving postsurgical adjuvant chemotherapy. Eur. J. Cancer 14:793-798, 1978.
 - 49. Mastrangelo, M.J., Berd, D. and Bellet, R.E. Limitations, obstacles and controversion in the optimal development of immunotherapy. In: Immunotherapy of Human Cancer, E. Hersh, J. Sinkovics (Editors), Raven Press, New York, NY, 1978, pp. 375-394.
 - 50. Bellet, R.E., Mastrangelo, M.J., Berd, D. and Lustbader, E. Melanoma chemotherapy.

 In: Cancer Chemotherapy III, I Brodsky, S.B. Kahn, J.F. Conroy (Editors),

 Grune and Stratton, Inc., New York, 1978, pp. 225-242.
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 Human Malignant Melanoma, Grune and Stratton, Inc., New York, 1979, pp. 489-496.
- 59. Laucius, J.F. and Mastrangelo, M.J. Cutaneous depigmentary phenomena in patients with malignant melanoma. In: Human Malignant Melanoma, Grune and Stratton, Inc., New York, 1979, pp. 209-226.
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 Cancer Res. 39:4472-4476, 1979.
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 In: Cancer Principles and Practices of Oncology, V.T. DeVita, S. Hellerman.

 S. Rosenberg (Editors), J.B. Lippincott, Co., Philadelphia, PA, 1982, pp. 1124-1187.
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 Immunological Aspects of Cancer Therapeutics, E. Mihich (Editor), John Wiley and Sons, Inc., NY, 1982, pp. 75-105.
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